

Institutional Review Board for Human Subjects Research (IRB/HSR)
California State University, Bakersfield
9001 Stockdale Highway, Bakersfield, CA 93311-1099

Minutes of Meeting
Friday, 22 September 2000
Old Pub/Runner Café

Members Present:

Scientific Concerns: Kaye Bragg, David Cohen (after 9:30), Peggy Leapley
Nonscientific Concerns: Steve Carter, Jeanne Harrie (until 9:30), Eun-Ja Park
Community Issues: Nancy Carr

Members Absent:

Amanda Bevier and Evelyn Johnson (both Community Issues)

Visitors Present:

Doris Hall, Laramee Lyda, and Jeff Craft for Protocol 00-40
Don Diboll for Protocols 00-41 and 99-14
Louanne Grode, Administrative Support Coordinator, Graduate Studies and Research
Edwin H. Sasaki, former IRB secretary
David Ost, Acting Dean of Graduate Studies and Research

1. Chair Jeanne Harrie called the meeting to order at 8:00 AM.
2. Ms. Louanne Grode, Administrative Support Coordinator, Graduate Studies and Research was introduced to the Board. Ms. Grode provides all the clerical support for the IRB/HSR, and she makes all arrangements for the quarterly meetings of the IRB/HSR.
3. The Chair noted several clerical corrections in the 02 June 2000 minutes. Steve Carter moved, and Kaye Bragg seconded, a motion to approve the minutes for the IRB/HSR meeting of 02 June 2000 with the clerical corrections to be forwarded to the IRB secretary. The motion to approve the minutes for 02 June 2000 with corrections was approved unanimously, with 6 “aye,” 0 “nay,” and 0 “abstentions.”
4. The Board considered formal affirmation of protocol approvals granted in between the April 2000 and June 2000 meetings of the IRB: protocols 00-15, 00-19, 00-25, 00-26, 00-27, 00-28, 00-29, 00-30, and 00-31. This action had been deferred from the 02 June 2000 meeting. Steve Carter moved and Peggy Leapley seconded a motion of formal affirmation. The motion was approved unanimously, with 6 “aye,” 0 “nay,” and 0 “abstentions.”
5. The Board considered formal affirmation of protocol approvals granted since the 02 June 2000 meeting: protocols 00-17, 00-32, 00-33, 00-34, 00-35, 00-36, 00-37, and 00-38. Steve Carter moved and Kaye Bragg seconded a motion of formal affirmation. The motion was approved unanimously, with 6 “aye,” 0 “nay,” and 0 “abstentions.”

6. There was discussion of replacing retroactive Board affirmations of closures already enacted by the IRB secretary with proactive Board affirmations to be enacted by the Board secretary at the proper time. Steve Carter moved and Kaye Bragg seconded such a motion. The motion was approved unanimously, with 6 “aye,” 0 “nay,” and 0 “abstentions.”
7. The Board considered formal closure of protocols whose one-year approval periods would expire prior to the next (January 2001) Board meeting. Steve Carter moved and Nancy Carr seconded such a motion. The motion was approved unanimously, with 6 “aye,” 0 “nay,” and 0 “abstentions.”
8. **[Standard Review] Protocol 00-40, "Cyberstalking: Is It a Problem at CSUB?"** with Dr. Doris Hall (Department of Criminal Justice), Laramee Lyda, and Jeff Craft. Dr. Hall explained that there is little research on the problem of cyberstalking in general and none involving non-traditional, commuter-oriented college campuses, such as CSUB. This research will involve non-random sampling of large numbers of CSUB students and a possible focus group if at least four stalkers are identified. Board members discussed the importance of providing potential subjects at the outset with more information about the project. Subjects considering involvement in the focus group should have more information as well. There was interest in the subject recruitment process in general and in particular the importance of protecting the anonymity of stalkers. Ms. Lyda summarized her experience with focus groups as a student, teaching assistant, and researcher. When there were no additional questions regarding the protocol, the investigators were excused. Following more discussion, it was decided to attach the following conditions to approval:
 - a. A consent form should be added as a cover page to the questionnaire, which would include detailed information about the nature of the research project.
 - b. The consent form for the focus group should include more specifics about the focus group activities, such as those included in Appendix E of the protocol.
 - c. Research-related activities in the classroom should be limited to explanation of the research and distribution of materials, so that questionnaires are not filled out in class, in order to preserve confidentiality.
 - d. Several names with contact information on consent forms should be corrected.

Nancy Carr moved, and Steve Carter seconded, a motion to grant conditional approval for Protocol 00-40. The motion was passed unanimously with 6 “aye,” 0 “nay,” and 0 “abstentions.”

Following approval, several specific suggestions were offered dealing with mechanisms for securing proper evidence of consent while protecting subject anonymity.

9. **[Standard Review] Protocol 00-41, "Aerobic Performance Fitness Assessments of Trained Adult Cyclists"** with Dr. Don Diboll (Department of Physical Education). Dr. Diboll explained that this research developed out of personal contacts with cyclists interested in assessment of their aerobic fitness. There are several potential comparisons possible with these data, including the direct aerobic assessment methods to be employed here with other "indirect" methods. The present (00-41) protocol is similar to protocol 99-14, except that older athletes are included in the present protocol and data collection is limited to oxygen consumption. There was considerable discussion of health risks because testing involves taking subjects to exhaustion. Pre-screeners will include those recommended by the American Academy of Sports Medicine. EKG will be monitored throughout. Sessions will only be conducted when a physician is on campus. The principal investigator is CPR certified. It was suggested that Dr. Diboll discover whether cardiac de-fibrillating equipment is present at the Health Center. When there were no additional questions regarding the protocol, the investigator was excused. Following more discussion, it was decided to attach the following conditions to approval:

- a. Include language in the consent form directly spelling out risks and the specific procedures to be undertaken in the event of such an emergency.
- b. Require the presence of at least two researchers, one of which must be CPR certified, at every data collection session.
- c. Work out a specific standard operating procedure in case of health emergency during testing in coordination with the Health Center, and conduct a "medical mock drill" of this procedure (including a response from the Health Center) prior to data collection.
- d. Indicate on the consent form that all of the personal data (except personal identity) and physiological data collected may be used for research purposes.
- e. Correct the Research Ethics Coordinator contact information on the consent form.

David Cohen moved, and Eun-Ja Park seconded, a motion to grant conditional approval for Protocol 00-41. The motion was passed with 5 "aye," 0 "nay," and 1 "abstention."

10. **[Extension] Protocol 99-14, "Cardiovascular and Metabolic Responses of Endurance-Trained Cyclists to Carbohydrate Consumption During Rest and Moderate-Intensity Exercise"** with Dr. Don Diboll. A motion to approve a written request for extension was approved without discussion, because Dr. Diboll has assured that there are no changes to the originally-approved protocol. David Cohen moved and Eun-Ja Park seconded. The motion was passed with 6 "aye," 0 "nay," and 0 "abstention."

11. The meeting concluded with a discussion of Board operating procedures, touching on:
 - (a) **Scheduling of Meetings.** There appeared to be support for continued scheduling of meetings very early in the academic quarter, but a consensus in favor of making possible a longer time period for Board members to review protocols.
 - (b) **Feedback to Investigators.** It was decided to encourage primary readers of protocols undergoing standard reviews to communicate specific protocol concerns to the Research Ethics Coordinator, who would attempt to relay a synthesis to the investigators, who may be able to react constructively to potential problems prior to the actual Board meeting. This will be tested on a trial basis for the January 2001 Board meeting.
 - (c) **Establishing Research Merit.** The scientific merit of proposed research is not always clearly established in the protocol and is, therefore, difficult to evaluate in order for Board members to carry out the necessary rationale cost/benefit analysis. David Cohen agreed to examine the Protocol Review Form and Instructions and submit, prior to the next Board meeting, suggested revisions which might better focus investigators on establishing the scientific merit of their research.
12. The next meeting will be Friday, 12 January 2001.
13. There being no further business, Acting Chair Kaye Bragg adjourned the meeting at 10:25 AM.

Respectfully submitted

Steve Suter, Ph.D.
Professor of Psychology
and IRB/HSR Secretary